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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ORION CORPORATION, Plaintiff/Counterclaim Defendant, v. SUN PHARMACEUTICAL INDUSTRIES LIMITED, Defendant/Counterclaim Plaintiff.	CIVIL ACTION NO. 3:07-cv-05436-MLC-JJH (Consolidated) **PUBLIC VERSION - REDACTED**

DEFENDANT SUN PHARMACEUTICAL INDUSTRIES, LIMITED'S
SECOND AMENDED ANSWER AND COUNTERCLAIMS

Defendant Sun Pharmaceutical Industries, Limited (hereinafter "Sun, Ltd." or "Defendant") hereby responds in this Second Amended Answer and Counterclaims to the allegations in the Complaint filed on November 13, 2007, by Plaintiff Orion Corporation (hereinafter "Orion" or "Plaintiff") as set forth below in response to the numbered paragraphs of the Complaint:

ANSWER

THE PARTIES

1. Sun, Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore denies them.

2. Sun, Ltd. admits that it is a public limited liability company incorporated and existing under the laws of India and having a principal place of business located at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

3. Sun, Ltd. admits that Sun Pharmaceutical Industries, Inc. (hereinafter, "Sun, Inc.") is a Michigan corporation and is a wholly-owned subsidiary of Sun, Ltd. Sun, Ltd. further admits that Sun, Inc. conducts business in the State of New Jersey at its offices located at 270 Prospect Plains Road, Cranbury, New Jersey 08512.

JURISDICTION AND VENUE

4. Sun, Ltd. admits that the Court has proper subject matter jurisdiction over the asserted claims. Sun, Ltd. admits that this purports to be an action for patent infringement arising under the patent laws of the United States. Sun, Ltd. admits that venue is proper in this judicial district.

5. Sun, Ltd. admits that it manufactures generic pharmaceuticals, but denies the allegation that it markets its generic pharmaceuticals throughout the United States, including the State of New Jersey.

6. Sun, Ltd. admits that the Court has personal jurisdiction over Sun, Ltd.

7. Sun, Ltd. admits that the Court has personal jurisdiction over Sun, Inc.

FACTUAL ALLEGATIONS

8. Sun, Ltd. admits that the face of the patent shows that United States Patent No. 6,500,867 ("the '867 patent") was issued on December 31, 2002. Sun, Ltd. is without knowledge or information sufficient to form a belief that the '867 patent was duly and legally issued, and therefore denies them. Sun, Ltd. is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

9. Sun, Ltd. admits that Orion is the holder a New Drug Application approved by the United States Food and Drug Administration (FDA) for the use of entacapone, levodopa, and carbidopa, but denies the remaining allegations of this paragraph.

10. Sun, Ltd. admits that Stalevo® is a combination of carbidopa, levodopa, and entacapone, but denies that Stalevo® is broadly approved by the FDA for the treatment of Parkinson's disease. Sun, Ltd. is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph, and therefore denies them.

11. Sun, Ltd. admits that it has submitted to the FDA an Abbreviated New Drug Application (ANDA) under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, importation, and sale of carbidopa, levodopa, and entacapone tablets, but denies that Sun, Ltd. filed the ANDA through Sun, Inc., denies that Sun, Inc. is an agent of Sun, Ltd., and denies that the ANDA seeks broad approval for treatment of Parkinson's disease. Sun, Ltd. admits the remaining allegations of this paragraph.

12. Sun, Ltd. admits to the allegations of paragraph 12 of the Complaint.

13. Sun, Ltd. admits that its counsel sent a letter dated September 27, 2007, to Orion to notify Orion that Sun, Ltd. had submitted an ANDA for carbidopa, levodopa, and entacapone

tablets and provided information pursuant to 21 U.S.C. 355(j)(2)(B)(ii). Sun, Ltd. further admits the letter was received by Orion on October 1, 2007.

14. Sun, Ltd. admits that Sun, Ltd.'s tablets will have the same indications as that of the FDA-approved Stalevo®. Because the ANDA seeks approval for fewer than all dosage strengths approved for Stalevo®, Sun, Ltd. denies that Sun, Ltd.'s tablet product package insert will have the same dosage instructions as those contained in the FDA-approved Stalevo® tablet product package insert.

COUNT I
PATENT INFRINGEMENT OF THE '867 PATENT

15. Sun, Ltd. incorporates by reference, as though fully set forth, paragraphs 1 through 14 herein.

16. Sun, Ltd. denies the allegations of paragraph 16 of the Complaint.

17. Sun, Ltd. denies the allegations of paragraph 17 of the Complaint.

18. Sun, Ltd. denies the allegations of paragraph 18 of the Complaint.

COUNT II
DECLARATORY JUDGMENT IN FAVOR OF THE '867 PATENT

19. Sun, Ltd. incorporates by reference, as though fully set forth, paragraphs 1 through 18 herein.

20. Sun, Ltd. denies the allegations of paragraph 20 of the Complaint.

21. Sun, Ltd. denies the allegations of paragraph 21 of the Complaint.

22. Sun, Ltd. denies the allegations of paragraph 22 of the Complaint.

23. Sun, Ltd. denies the allegations of paragraph 23 of the Complaint.

COUNT III
EXCEPTIONAL CASE

24. Sun, Ltd. incorporates by reference, as though fully set forth, paragraphs 1 through 23 herein.

25. Sun, Ltd. denies the allegations of paragraph 25 of the Complaint.

26. Sun, Ltd. denies the allegations of paragraph 26 of the Complaint.

PRAYER FOR RELIEF

The allegations contained in the Prayer for Relief do not require a response, but to the extent that the Prayer for Relief contains additional allegations, Sun, Ltd. denies them all and denies that Orion is entitled to any relief from Sun, Ltd. Wherefore, Sun. Ltd demands Judgment dismissing plaintiff's Complaint.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

27. Orion's Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Failure to Join Necessary and/or Indispensable Parties)

28. Orion's claims are barred because it has failed to join necessary and/or indispensible parties.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of the '867 Patent)

29. Sun, Ltd. is not infringing, has not infringed, and will not infringe, directly or indirectly, any valid and enforceable claim of the '867 patent, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE
(Unenforceability of the '867 Patent)

Applicants' duty to the USPTO

30. Applicants had a duty to disclose to the U.S. Patent and Trademark Office (USPTO) any information that is material to the patentability of any claim being prosecuted under 37 C.F.R. § 1.56, which states as follows:

> Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned.

(37 C.F.R. § 1.56).

31. Persons substantively involved in the preparation or prosecution of the application leading to the '867 patent-in-suit and who are associated with the Inventor(s) of the '867 patent, with the assignee, or with anyone to whom there is an obligation to assign the application leading to the '867 patent-in-suit had a duty to prosecute the application with candor, good faith and honesty.

32. The Inventors of the'867 patent-in-suit and their agents (hereinafter referred to as "Applicants") had a duty to prosecute the '867 patent application with candor, good faith and honesty.

33. Persons substantively involved in the preparation or prosecution of the application leading to the '867 patent-in-suit and who were associated with the Inventor(s) of the '867 patent, with the assignee, or with anyone to whom there was an obligation to assign the

application leading to the '867 patent-in-suit had a duty to disclose material information during the prosecution of the ' 867 patent application.

34. The Applicants of the '867 patent-in-suit and their agents had a duty to disclose material information relating to the patentability of the '867 patent-in-suit during the prosecution of the application that became the '867 patent.

35. Applicants also had an affirmative obligation to inform the USPTO of any information of which Applicants were aware that was contrary to affirmative statements made to the during prosecution of the patents-in-suit.

36. Under 37 C.F.R. § 1.56(b), information is material to patentability when it is not cumulative to information already of record or being made of record in the application and/or it refutes or is inconsistent with a position an applicant takes in opposing an argument of unpatentability relied upon by the USPTO or asserting an argument of patentability.

37. The violation of an applicant's duties and obligations to the USPTO, such as intentionally withholding material information from the USPTO, with intent to deceive, constitutes inequitable conduct.

Applicants' Intentional Misdirection on the Obviousness Issue Specifically Relating to Claim 12

38. Claim 12 of the '867 patent states:

> A ***stable*** oral solid tablet composition ***comprising pharmacologically effective amounts of entacapone, levodopa and carbidopa***, or pharmaceutically acceptable salts or hydrates thereof, wherein a substantial portion of the carbidopa or pharmaceutically acceptable salt or hydrate thereof is separated from the entacapone and levodopa or pharmaceutically acceptable salts or hydrates thereof in the tablet, and comprising at least one pharmaceutically acceptable excipient ***other than microcrystalline cellulose***.

('867 patent, col. 12, lns. 50-58)(emphasis added).

39. The Examiner rejected claim 12 (listed as claim 11 during the prosecution of the '867 patent) along with claims 1-4, 7, 9, 12-23 as being unpatentable under 35 U.S.C. § 103(a) over Dempski *et al.* (EP 253490) in view of Woodcock (GB 2321190).

40. Dempski *et al.* discloses treating Parkinson's with "a matrix or monolithic drug delivery system for the controlled release of carbidopa and levodopa…" (EP 253490 at p.1).

41. Woodcock discloses treating Parkinson's disease with entacapone. (*See generally* GB 2321190).

The Examiner argued that:

> It would have been obvious to one having ordinary skill in the art to modify the compositions/method taught by Dempski to include the entacapone taught by Woodcock. One would have been motivated to do this since both compositions/methods are geared toward the treatment of Parkinson's disease. In a claim drawn to preparation, the ***simple act of combining and mixing ingredients in various orders has no patentable weight***. The optimal amounts would have been ***determined through routine experimentation***.

(Office Action in U.S. Patent Application No. 09/605,529 dated August 14, 2001; see p. 2) (emphasis added).

42. Regarding claim 12, Applicants argued that they *surprisingly* encountered unexpected problems during the development of their entacapone/levodopa/carbidopa formulation:

> Claim 11 [claim 12 of the '867 patent] recites a stable oral solid composition comprising entacapone, levodopa and carbidopa, and at least one excipient ***other than microcrystalline cellulose***. The art did not suggest making such a composition. ***Instead the art most likely would have suggested using such amounts of microcrystalline cellulose that would have destabilized entacapone/levodopa/carbidopa solid compositions.***
>
> As explained in the specification, the co-formulation of ***substantial amounts*** of microcrystalline cellulose with entacapone/levodopa/ carbidopa can ***destabilize*** the formulation ***on long term storage***. Specification at page 9, lines 18-21. ***This would have been surprising to one skilled in the art, given the widespread use of microcrystalline cellulose as a carrier in oral pharmaceutical formulations.*** In contrast to what the art would have suggested, the invention of claim 11 includes, aside from the combination of active agents, at least one

> excipient other than microcrystalline cellulose, wherein the composition is stable. Claim 11 should thus be patentable over the art. (emphasis added).

(Office Action Response dated February 13, 2002; see pp. 7-8) (emphasis added).

43. By arguing that it was surprising to one skilled in the art that microcrystalline cellulose was an unsuitable excipient, Applicants intentionally misled the USPTO because they failed to disclose that, under the conditions in which Applicants utilized microcrystalline cellulose (*i.e.*, wet granulation), it was well known by Applicants, and the art recognized that under certain conditions, that moisture can degrade microcrystalline cellulose, therefore affecting the properties of active pharmaceutical ingredients ("APIs").

44. It would ***not*** have been surprising to one skilled in the art, even in light of the widespread use of microcrystalline cellulose as a carrier in oral pharmaceutical formulations, that microcrystalline cellulose used in the wet granulation manufacturing method was employed by Applicants would have destabilized the APIs, *i.e.*, entacapone/levodopa/carbidopa in the formulation.

All claims are unduly broad and were obtained by misdirection because it was well known that microcrystalline cellulose in the presence of excess moisture degrades APIs and carbidopa is sensitive to moisture, material information which was withheld from the examiner

45. It was well known to Applicants, before both the filing of the Finnish priority document and the '867 application, that that the art recognized microcrystalline cellulose to be hygroscopic, *i.e.*, it readily retains water, thereby potentially exposing moisture-sensitive APIs to harmful degradation.

46. It was also known in the art, well before the '867 patent application was filed, that moisture absorbed by microcrystalline cellulose could degrade moisture-sensitive APIs, *e.g.*, TAT-59, aspirin, ketorolac, ascorbic acid, and paracetamol. (*See* Matsunaga *et al.*, *Effects of*

Compression Pressure on Physical and Chemical Stability of Tablets Containing an Anticancer Drug TAT-59, Chem. Pharm. Bull. 42(12): 2582-2587 (1994)). (SUN 045273 – 278).

47. It was also known in the art that tableting properties, such as tablet strength, can be negatively affected by increased moisture content within microcrystalline cellulose. (Doelker, *Comparative Compaction Properties of Various Microcrystalline Cellulose Types and Generic Products*, Drug Dev. Indust. Pharm. 19(17&18): 2399-2471 (1993)). (SUN 045279 – 315).

48. ** HIGHLY CONFIDENTIAL – REDACTED **

49. It was also known in the prior art to use low moisture content microcrystalline cellulose when working with moisture sensitive APIs, *e.g.*, U.S. Patent 6,376,545 (issued April 23, 2002, based upon provisional application filed November 10, 1998) specifically discloses using microcrystalline cellulose with a moisture content of less than or equal to 5% in conjunction with formulations containing carbidopa.

50. The prior art also recognized that carbidopa was highly sensitive to moisture. (*See* Pappert *et al.*, *The Stability of Carbidopa in Solution*, Movement Disorders, Vol. 12, No. 4:608-610, 1997).

51. ** HIGHLY CONFIDENTIAL – REDACTED **

52. ** HIGHLY CONFIDENTIAL – REDACTED **

53. Despite this knowledge, Applicants intentionally mislead the USPTO into believing that it was "surprising" that microcrystalline cellulose destabilized the entacapone/levodopa/carbidopa formulation.

54. ** HIGHLY CONFIDENTIAL – REDACTED **

55. ** HIGHLY CONFIDENTIAL – REDACTED **

56. Carbidopa, which had been publicly sold in combination with levodopa since the mid 1990's was known to be sensitive to moisture and that it should be protected from exposure to moisture. The Applicants, like those skilled in the art of formulating, therefore knew (or should have known) that carbidopa was moisture sensitive.

57. ** HIGHLY CONFIDENTIAL – REDACTED **

58. Steven Scott, prosecuting attorney for the '867 application (who at the time of the pendency of the '867 application was employed at Finnegan Henderson LLP) also knew, or should have known, based on communications with Applicants, of the effects of moisture on microcrystalline cellulose and resulting effects of moisture on APIs and that carbidopa was an API that was sensitive to moisture. Mr. Scott failed to disclose this highly material information to the USPTO.

59. Finnegan Henderson LLP lawyers Bryan Diner and/or T. Naukarinen were directly involved in providing Applicants with advice as to the preparation of both U.S. and foreign patent applications involving the composition containing entacapone/levodopa/carbidopa including the '867 patent application.

60. Mr. Diner and/or Mr. Naukarinen knew or should have known of the effects of moisture on microcrystalline cellulose and resulting effects of moisture on APIs and that carbidopa was an API that was sensitive to moisture. Mr. Diner and/or Mr. Naukarinen failed to disclose this highly material information to the USPTO.

61. Arja Weckman, in-house counsel for Plaintiff Orion, had direct communications with Applicants before and during the prosecution of the '867 patent application and was directly involved in providing Applicants with advice as to the preparation of both U.S. and foreign

patent applications involving the composition containing entacapone/levodopa/carbidopa including the '867 patent application.

62. Ms. Weckman knew or should have known of the effects of moisture on microcrystalline cellulose and resulting effects of moisture on APIs and that carbidopa was an API that was sensitive to moisture. Ms. Weckman failed to disclose this highly material information to the USPTO.

63. The known effects of moisture on microcrystalline cellulose and resulting effects of moisture on APIs should have been disclosed to the USPTO because it would have been material to, and directly contradicted, Applicants' argument that the destabilization of a formulation of entacapone/levodopa/carbidopa with microcrystalline cellulose was "surprising".

Microcrystalline Cellulose exacerbated degradation of carbidopa when wet granulation was used, which was known to Applicants but withheld from the Examiner

64. ** HIGHLY CONFIDENTIAL – REDACTED **

65. ** HIGHLY CONFIDENTIAL – REDACTED **

66. ** HIGHLY CONFIDENTIAL – REDACTED **

67. ** HIGHLY CONFIDENTIAL – REDACTED **

68. ** HIGHLY CONFIDENTIAL – REDACTED **

69. ** HIGHLY CONFIDENTIAL – REDACTED **

70. ** HIGHLY CONFIDENTIAL – REDACTED **

71. ** HIGHLY CONFIDENTIAL – REDACTED **

72. ** HIGHLY CONFIDENTIAL – REDACTED **

73. As noted above, in order to overcome a rejection under 35 U.S.C. § 103 during the prosecution of the '867 patent application, Applicants argued that "as explained in the specification, the co-formulation of substantial amounts of microcrystalline cellulose with

entacapone/levodopa/ carbidopa can destabilize the formulation on long term storage" and that it would "have been surprising to one skilled in the art, given the widespread use of microcrystalline cellulose as a carrier in oral pharmaceutical formulations."

74. According to Orion's response to Sun's Interrogatory Nos. 5 and 6, Orion states that the test results of batch MTY66-Z09-02 form the basis for the conclusion of Applicants' argument that the "co-formulation of substantial amounts of microcrystalline cellulose with entacapone/levodopa/ carbidopa can destabilize the formulation on long term storage" and the conclusion that it would "have been surprising to one skilled in the art, given the widespread use of microcrystalline cellulose as a carrier in oral pharmaceutical formulations."

75. ** HIGHLY CONFIDENTIAL – REDACTED **

76. ** HIGHLY CONFIDENTIAL – REDACTED **

77. ** HIGHLY CONFIDENTIAL – REDACTED **

78. ** HIGHLY CONFIDENTIAL – REDACTED **

79. ** HIGHLY CONFIDENTIAL – REDACTED **

80. ** HIGHLY CONFIDENTIAL – REDACTED **

81. ** HIGHLY CONFIDENTIAL – REDACTED **

82. ** HIGHLY CONFIDENTIAL – REDACTED **

83. ** HIGHLY CONFIDENTIAL – REDACTED **

84. ** HIGHLY CONFIDENTIAL – REDACTED **

85. Mr. Naukarinen was directly involved in providing Applicants with advice as to the preparation of both U.S. and foreign patent applications involving the composition containing entacapone/levodopa/carbidopa, including the '867 patent application.

86. Orion's in-house counsel, Arja Weckman, had direct communication with Applicants before and during the prosecution of the '867 patent application and was directly involved in providing Applicants with advice as to the preparation of both U.S. and foreign patent applications involving the composition containing entacapone/levodopa/carbidopa, including the '867 patent application.

87. ** HIGHLY CONFIDENTIAL – REDACTED **

88. Bryan Diner, of the law firm Finnegan Henderson LLP, had direct communications with Applicants before and during the prosecution of the '867 patent application and was directly involved in providing Applicants with advice as to the preparation of both U.S. and foreign patent applications involving the composition containing entacapone/levodopa/carbidopa, including the '867 patent application.

89. ** HIGHLY CONFIDENTIAL – REDACTED **

90. The instability of the invention was not a generalized problem as the '867 patent claims are broadly drafted to suggest, but rather a problem specific to a wet, high shear granulation manufacturing process.

91. This clear understanding was never disclosed to the USPTO during the prosecution of the '867 patent, nor is there any disclosure that the wet, high shear granulation manufacturing method played a central role in the instability of the formulation.

92. Applicants and prosecuting attorney Mr. Scott, in their arguments to the USPTO, stated that the prior art "most likely would have suggested using such amounts of microcrystalline cellulose that would destabilize entacapone/levodopa/carbidopa solid compositions."

93. ** HIGHLY CONFIDENTIAL – REDACTED **

94. Applicants had themselves previously published articles on the known problems posed by using microcrystalline cellulose in a wet granulation method prior to and throughout the prosecution of the '867 patent application.

95. An article entitled *Microcrystalline cellulose and its microstructure in pharmaceutical processing* (1999) was co-authored by inventor Lasse Kervinen (SUN 45205 – 212) and published well before the filing of the application that resulted in the '867 patent. This article extensively discusses the adverse effects of wet granulation on microcrystalline cellulose.

96. A thesis entitled *Use of Mercury Porosimetry and Nitrogen Adsorption in Characterisation of the Pore Structure of Mannitol and Microcrystalline Cellulose Powders, Granules, and Tablets* (SUN 045213 – 272) written in October 2000 (*i.e.*, before the Office Action response of February 13, 2002) under the supervision of inventors Marja Ritala, Mervi Niskanen, and Lasse Kervinen further demonstrates that the inventors were aware of the detrimental effects of moisture on microcrystalline cellulose.

97. Despite this knowledge, Applicants intentionally mislead the USPTO into believing that it was "surprising" that microcrystalline cellulose destabilized the formulation containing entacapone, levodopa and carbidopa.

98. Applicants knew there was nothing surprising or unexpected about the fact that microcrystalline cellulose would destabilize the formulation because they knew that it was public knowledge that carbidopa was moisture sensitive, and that microcrystalline cellulose absorbed/adsorbed potentially detrimental amounts of moisture, and this information directly contradicted any allegation of unexpected destabilization.

99. ** HIGHLY CONFIDENTIAL – REDACTED **

100. No prior art describing the high tendency of microcrystalline cellulose to absorb large amounts of moisture, or that carbidopa degraded in the presence of moisture was ever disclosed to the Examiner, in any of the Information Disclosure Statements, dated September 11, 2000, February 13, 2002 (filed the same date as the Office Action response of February 13, 2002), February 19, 2002, and June 11, 2002.

101. This highly material information, that moisture has a detrimental effect on microcrystalline cellulose and carbidopa, was intentionally withheld from the Examiner so that Applicants could make the misleading argument that it was "surprising" that microcrystalline cellulose "destabilized" the entacapone/levodopa/carbidopa formulation in order to overcome the prior art asserted by the Examiner.

102. ** HIGHLY CONFIDENTIAL – REDACTED **

103. Applicants knew throughout the prosecution of the '867 patent application that the process they employed for their formulation, *i.e.*, wet granulation, led directly to the instability/degradation described in the patent but intentionally withheld this information from the USPTO.

104. Applicants' lack of candor is reinforced by the disclosure of a patent application by Giovanni Politi, a member of the Stalevo® development team at Orion, U.S. Publication No. 2006/0222703 ("Politi Application"; SUN045316-320).

105. ** HIGHLY CONFIDENTIAL – REDACTED **

106. The Politi Application expressly confirms that large amounts of microcrystalline cellulose is not a viable excipient when wet granulation is employed, but that in the absence of wet granulation, microcrystalline cellulose may be used. (Politi Application paragraphs 5 and 10).

107. At no point during the prosecution of the '867 patent application did Applicants or their Counsel inform the Examiner of the highly material information that stability problems regarding any of the APIs was caused by the absorption of moisture by microcrystalline cellulose during the wet granulation method, even though it was known, or should have been known to them.

108. The deleterious effects of moisture on microcrystalline cellulose were well documented in the art and known to Applicants before and during the filing and prosecution of the '867 application.

109. The deleterious effects of moisture on carbidopa were well known to the '867 patent Applicants.

110. Applicants and their Counsel intentionally concealed from the USPTO during the prosecution of the '867 patent application, that the wet granulation manufacturing method in conjunction with microcrystalline cellulose would have been expected by those of skill in the art to lead to instability of the carbidopa in the formulation, even though they knew or should have known this was the case.

111. Applicants of the '867 patent application violated of their duty to disclose material information during the prosecution of the '867 patent application because they intentionally withheld from the USPTO highly material information of which they were aware and that was contrary to affirmative statements made to the USPTO.

112. Had Applicants and their Counsel disclosed to the USPTO the detrimental effect of moisture absorbed by microcrystalline cellulose, resulting from the wet granulation method, which caused the carbidopa to degrade, and had informed the USPTO that it was well known

that water sensitive ingredients, specifically including carbidopa, degrade in the presence of moisture, a reasonable Examiner would have maintained his obviousness rejection.

113. The Examiner already realized that "the ***simple act of combining and mixing ingredients in various orders has no patentable weight***. The optimal amounts would have been ***determined through routine experimentation***." (Office Action in U.S. Patent Application No. 09/605,529 dated August 14, 2001) (emphasis added).

In light of the detrimental effects of water on microcrystalline cellulose and carbidopa, the '867 patent was obvious, something known to the Applicants

114. Applicants' employer, Orion, owns U.S. Patent No. 5,112,861 ("the '861 patent") (issued May 12, 1992), which disclosed and claimed an entacapone/levodopa/carbidopa formulation and method of treating Parkinson's disease. (*See* '861 patent col. 8 lns. 22-31; col. 38 lns. 7-18; SUN 045105 – 127).

The '861 patent specifically states:

> For the ***treatment of Parkinson's disease the compounds according to formula I [entacapone] are given with levodopa***, each in its own composition or ***combined in one composition. Also***, peripheral dopa decarboxylase (DDC) inhibitors, such as ***carbidopa . . . may be present*** . . . .

(*See* '861 patent col. 8 lns. 25-31; SUN 045105 – 127)(emphasis added).

115. Given the specific disclosure in the '861 patent regarding a single formulation tablet of entacapone/carbidopa/levodopa, Applicants and their Counsel intentionally sought to downplay the obviousness of such a formulation by misrepresenting the problems which their formulation as "surprising" and "unexpected."

116. The instability of carbidopa resulting from wet granulation was not surprising or unexpected to one of skill in the art as of the time of the invention.

117. The instability of carbidopa as a result of the use of substantial amounts of microcrystalline cellulose in combination with wet granulation was not surprising to one of skill in the art as of the time of the invention.

118. As of the date of invention of the '867 patent, one of skill in the art, practicing routine experimentation would not have been motivated to use substantial amounts of microcrystalline together with wet granulation.

119. Had Applicants and their Counsel been candid with the Examiner, following the teachings of the '861 patent, a reasonable Examiner would have maintained that using routine experimentation, one of skill in the art would have realized that if microcrystalline cellulose is used in a wet granulation process, routine steps known in the art to separate moisture from carbidopa would have been employed as Orion's own patent clearly suggests. Thus, the Examiner would thus have maintained his rejection under 35 U.S.C. § 103.

The '867 patent is unenforceable

120. The foregoing false statements, omissions and misrepresentations made by the Applicants and their attorneys set forth above were made with an intent to deceive the USPTO and did mislead the USPTO into allowing the '867 patent thereby rendering all claims of the '867 patent unenforceable.

FIFTH AFFIRMATIVE DEFENSE
(Prosecution History Estoppel)

121. Any claim by Orion that the claims of the '867 patent cover and include the products or acts of Sun, Ltd. are barred by the doctrine of prosecution history estoppel or otherwise by virtue of admissions, amendments, arguments, representations and/or

misrepresentations made to the United States Patent and Trademark Office during the prosecution of the application from which the '867 patent issued.

SIXTH AFFIRMATIVE DEFENSE
(Unclean Hands)

122. Orion is barred from any recovery because of unclean hands.

COUNTERCLAIMS

Counterclaimant Sun Pharmaceutical Industries Limited ("Sun, Ltd."), by way of Counterclaim for Declaratory Judgment against Orion Corp. ("Orion"), alleges as follows:

I. THE PARTIES

1. Counterclaimant Sun, Ltd. is a public limited liability company incorporated and existing under the laws of India with its principal place of business in Mumbai, India.

2. Upon information and belief, Counterclaim Defendant Orion is a corporation organized and existing under the laws of Finland with its principal place of business in Espoo, Finland.

II. THE PATENT-IN-SUIT

3. The patent-in-suit is United States Patent No. 6,500,867 ("the '867 patent"), issued on December 31, 2002. Sun, Ltd. submitted Paragraph IV certifications pursuant to 21 U.S.C. § 355(j), filed in conjunction with Sun, Ltd.'s ANDA listed the '867 patent and United States Patent No. 6,797,732 ("the '732 patent"), issued on September 28, 2004. Originally, Sun sought declaratory relief pursuant to pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(I) for non-infringement and invalidity of the '732 patent because Orion had not asserted the '732 patent within the requisite 45-day period under the Hatch-Waxman Act. Pursuant to a covenant-not-to sue on the '732 patent, the '732 patent is no longer in-suit.

III. JURISDICTION AND VENUE

4. Counterclaimant Sun, Ltd. brings this action for a declaratory judgment of patent non-infringement against Orion. This action arises under the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and the Patent Laws of the United States of America, 35 U.S.C. §§ 101, *et seq.*

5. Orion submitted to the U.S. Food and Drug Administration ("FDA") the '867 patent and the '732 patent for listing in "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for Stalevo®.

6. On October 1, 2007, Orion received from Sun, Ltd. a notice letter pursuant to 21 U.S.C. § 355 (j)(2)(B) ("Notice") indicating that Sun, Ltd.'s ANDA No. 79-085 was filed, and that the ANDA included Paragraph IV certifications for both the '867 patent and the '732 patent. The Notice related, *inter alia,* to non-infringement, and included an Offer of Confidential Access to the ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

7. Orion has filed a complaint against Sun, Ltd. for infringement of the '867 patent.

8. A justiciable controversy exists for the '867 patent because Orion has asserted patent infringement of the '867 patent in this District Court.

9. Subject matter jurisdiction over the counterclaims is proper pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Orion is subject to general personal jurisdiction in this judicial district. Moreover, Orion has purposefully availed itself of the privileges of this District through the filing of a complaint in this District alleging infringement of the '867 patent. Venue is proper in this District under 28 U.S.C. §§ 1391(c) or (d).

IV. FACTUAL ALLEGATIONS

11. 21 U.S.C. § 355 (b)(1) and 21 C.F.R. 314.53(b) require the applicant of a New Drug Application ("NDA") to submit to FDA patents that, among other requirements, claim the drug for which the NDA applicant submitted the NDA, or that claim a method of using such drug. FDA publishes submitted patents in the Orange Book.

12. A patent should not be submitted for listing in the Orange Book if it does not claim the approved drug or an approved method of using the drug. *See, e.g.*, 21 U.S.C. § 355 (b)(1), 21 C.F.R. 314.53(b).

13. All claims of the '867 patent recite that a substantial portion of carbidopa is separated from levodopa and entacapone.

14. The final printed label approved by FDA for the product Stalevo does not indicate that the carbidopa is separated from the levodopa and entacapone.

15. FDA has published documents relating to approval of the Stalevo NDA (http://www.fda.gov/cder/foi/nda/2003/21-485_Stalevo.htm). In the Chemical Review published by FDA (http://www.fda.gov/cder/foi/nda/2003/21-485_STALEVO_Chemr.pdf), Orion had redacted, or authorized redaction of, among other portions, the entire "Chemistry Assessment" section, including the entire subsections on the active ingredients, on the dosage form, and on the method of manufacturing the dosage form. The remaining un-redacted portions published by FDA do not indicate that the carbidopa is separated from the levodopa or entacapone.

16. Upon information and belief, the carbidopa in the Orion product Stalevo is not separated from the levodopa or entacapone.

17. Upon information and belief, independent composition claim 1 of the '867 patent does not recite the drug product for which NDA 21-485 was approved.

18. Upon information and belief, independent composition claim 5 of the '867 patent does not recite the drug product for which NDA 21-485 was approved.

19. Upon information and belief, independent composition claim 12 of the '867 patent does not recite the drug product for which NDA 21-485 was approved.

20. Upon information and belief, independent method claim 13 of the '867 patent does not recite an FDA-approved method of using Stalevo.

21. Upon information and belief, independent method claim 14 of the '867 patent does not recite an FDA-approved method of using Stalevo.

22. Upon information and belief, independent method claim 17 of the '867 patent does not recite an FDA-approved method of using Stalevo.

23. Upon information and belief, independent method claim 19 of the '867 patent does not recite an FDA-approved method of using Stalevo.

24. Upon information and belief, independent composition claim 21 of the '867 patent does not recite the drug product for which NDA 21-485 was approved.

25. Upon information and belief, independent composition claim 23 of the '867 patent does not recite the drug product for which NDA 21-485 was approved.

26. Upon information and belief, independent composition claim 25 of the '867 patent does not recite the drug product for which NDA 21-485 was approved.

27. Upon information and belief, the '867 patent does not claim either the drug for which NDA 21-845 was approved, or an FDA-approved method of using the drug.

FIRST COUNTERCLAIM
DECLARATORY JUDGMENT OF NONINFRINGEMENT

28. The allegations of paragraphs 1 – 122 of the Answer and paragraphs 1-27 of the Counterclaims are incorporated by reference herein.

29. Counterclaimant Sun, Ltd. has not, does not, and will not directly infringe, contributorily infringe or induce others to infringe any valid claim of the '867 patent, either literally or under the doctrine of equivalents. Accordingly, Sun, Ltd. is entitled to declaratory judgment of noninfringement of the '867 patent.

SECOND COUNTERCLAIM
DECLARATORY JUDGMENT OF INVALIDITY

30. The allegations of paragraphs 1 – 122 of the Answer and paragraphs 1-29 of the Counterclaims are incorporated by reference herein.

31. No claim of the '867 patent found to be infringed would be valid under 35 U.S.C. §§ 101 *et seq.*

THIRD COUNTERCLAIM
DECLARATORY JUDGMENT OF UNENFORCEABILITY

32. The allegations of paragraphs 1 – 122 of the Answer and paragraphs 1 – 31 of the Counterclaims are incorporated by reference herein.

33. The '867 patent is unenforceable due to inequitable conduct.

FOURTH COUNTERCLAIM
DELISTING OF THE '867 PATENT

34. The allegations of paragraphs 1 – 122 of the Answer and paragraphs 1 – 33 of the Counterclaims are incorporated by reference herein.

35. The listing of the '867 patent in the Orange Book should be deleted under 21 U.S.C. § 355 (j)(5)(C)(ii).

PRAYER FOR RELIEF

WHEREFORE, Counterclaimant Sun, Ltd. seeks a declaratory judgment against Orion as follows:

1. Dismissing the Complaint for Patent Infringement of the '867 patent against Sun, Ltd. in its entirety, with prejudice, and that Orion shall take nothing by the Complaint, and that judgment be entered in favor of Sun, Ltd.;

2. Declaring that Sun, Ltd. has not, does not, and will not infringe the '867 patent;

3. Declaring that Sun, Ltd. has not, does not, and will not induce and/or engage in contributory infringement of the '867 patent;

4. Declaring that the all the claims of the '867 patent are invalid;

5. Declaring that the '867 patent is unenforceable;

6. Ordering that Orion delete the listing of the '867 patent in the Orange Book;

7. Declaring this case exceptional under 35 U.S.C. § 285;

8. Awarding Sun, Ltd. its Costs and Attorneys fees; and

9. Awarding Sun, Ltd. such other and further relief as the Court may deem just and proper.

Dated: January 27, 2009

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By: _____

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